



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 1, 2020

Michael Rekhelman
VP Technical Services
ABC Compounding Co., Inc.
2600 Dogwood Dr
Conyers, GA 30013

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Disinfectant Spray II
EPA Registration Number: 3862-188
Application Date: June 8, 2020
Decision Number: 563746

Dear Mr. Rekhelman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup are small non-enveloped, large non-enveloped, enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus and Rhinovirus Type 37 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

ACCEPTED

09/01/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 3862-188

DISINFECTANT SPRAY II
Surface Disinfectant and Deodorizer

A BROAD-SPECTRUM DISINFECTANT FOR
ENVIRONMENTAL SURFACES.
ELIMINATES ODORS BY ATTACKING THEM AT THEIR SOURCE.

DISINFECTANT – TUBERCULOCIDAL - *VIRUCIDAL

DESINFECTANTE

SI USTED NO ENTIENDE LA ETIQUETA, BUSQUE A ALGUIEN PARA QUE SE
LA EXPLIQUE A USTED EN DETALLE.
(IF YOU DO NOT UNDERSTAND THIS LABEL, FIND SOMEONE TO EXPLAIN IT
TO YOU IN DETAIL)

ACTIVE INGREDIENTS:

Orthophenylphenol:.....0.08%

INERT INGREDIENTS:.....99.92%

TOTAL:..... 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

CONTENTS UNDER PRESSURE

SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

EPA REG. NO. 3862-188 EPA EST. NO.

NET WT.:

MANUFACTURED BY:
ABC COMPOUNDING CO., INC.
P.O. BOX 16247
ATLANTA, GA 30321

TUBERCULOCIDAL ACTIVITY: This product exhibits disinfectant efficacy against *Mycobacterium bovis* (BCG) in 3 minutes at 20° C when used as directed on hard, nonporous, inanimate surfaces in the presence of 5% blood serum. **BACTERICIDAL AND *VIRUCIDAL ACTIVITY:** This product exhibits disinfectant efficacy in 3 minutes against the following organisms when used as directed on hard, non-porous, inanimate surfaces in the presence of 5% blood serum: *Pseudomonas aeruginosa* (ATCC 15442), *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), Methicillin-Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), Influenza A2 Virus (A/2/Japan/305/57, strain H2N2), Human Immunodeficiency Virus Type 1 (HIV-1) (strain IIIB), Herpes Simplex Virus Type 2 (strain G, ATCC VR-734), Human Coronavirus (ATCC VR-740, Strain 229E), Feline Calicivirus (ATCC VR-782, Strain F-9), Norovirus (Norwalk virus), and Rhinovirus type 37 (ATCC VR-1147, Strain 151-1). ***KILLS HIV ON PRE-CLEANED HARD, NON-POROUS SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1. **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.** **Personal Protection:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye protection. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of this product. **Disposal of Infectious Materials:** Blood and other body fluids, cleaning materials and clothing must be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal. **Contact Time:** Allow surfaces to remain wet for 3 minutes.

Disinfects and controls odors on hard, nonporous surfaces such as metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathroom fixtures, shower stalls, empty garbage cans and diaper pails, furniture in sick rooms and nurseries, fishing equipment and sports equipment.

USED IN: HOSPITALS AND OTHER MEDICAL, INDUSTRIAL, INSTITUTIONAL, COMMERCIAL AND RESIDENTIAL FACILITIES.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. *(Use one of the following two statements below):*

This product is not for use on critical or semi-critical medical device surfaces.

(or)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

HOLD CONTAINER UPRIGHT. SHAKE OCCASIONALLY DURING USE.
 FOR TUBERCULOCIDAL USE: Remove visible soil and spray from 6-8” until thoroughly wet. Allow surface to remain undisturbed for at least 3 minutes at 20° C before wiping.
 FOR DISINFECTING and deodorizing: remove visible soil and spray from 6-8” until thoroughly wet. Allow surface to remain undisturbed for at least 3 minutes before wiping. For use against HIV-1 see special instructions for cleaning.

(Note to Reviewer: These statements for claims against emerging viral pathogens shall not appear on marketed (final print) product labels.)

Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below:

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses*
- Large Non-Enveloped Viruses*
- Small Non-Enveloped Viruses*

| | |
|---|---|
| <i>For an emerging viral pathogen that is a/an...</i> | <i>...follow the directions for use for the following organisms on the label:</i> |
| <i>Enveloped virus</i> | <i>Rhinovirus Type 37 Feline Calicivirus</i> |
| <i>Large, non-enveloped virus</i> | <i>Rhinovirus Type 37 Feline Calicivirus</i> |
| <i>Small, non-enveloped virus</i> | <i>Rhinovirus Type 37 Feline Calicivirus</i> |

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus and Rhinovirus Type 37 on hard non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus and Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

STORAGE AND DISPOSAL

GENERAL: Do not contaminate other materials, including water, food or feed during transport, use, storage, or disposal. If damaged or leaking, soak up and wrap waste, then dispose of as below. **Storage:** Keep in a cool, dry, locked area inaccessible to children and away from flames, sparks, sunlight, or other sources of heat or ignition. Containers heated above 130°F (54°C) may burst. **Disposal:** Refasten protective cap on container and discard in trash or offer for recycling, if available. Do not incinerate or puncture.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear safety gloves and glasses. Do not spray on or toward eyes or face. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Do not contaminate food or feed, nor surfaces that they may contact.

| FIRST AID: | |
|--|---|
| If swallowed | <ul style="list-style-type: none">● Call a poison control center or doctor for further treatment advice.● Have person sip a glass of water if able to swallow.● Do not induce vomiting unless told to do so by the poison control center or doctor.● Do not give anything by mouth to an unconscious person. |
| If on skin or clothing | <ul style="list-style-type: none">● Take off contaminated clothing.● Rinse skin immediately with plenty of water for 15-20 minutes.● Call a poison control center or doctor for further treatment advice. |
| If in eyes | <ul style="list-style-type: none">● Hold eye open and rinse slowly and gently with water for 15-20 minutes.● Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.● Call a poison control center or doctor for further treatment advice. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. | |

PHYSICAL AND CHEMICAL HAZARDS

Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not use this product in or on electrical equipment due to the possibility of shock hazard.